REMARKS

The Official Action of June 30, 2006, and the prior art relied upon therein have been carefully reviewed. The claims in the application are now only claims 10 and 15-19, and these claims recite patentable subject matter and therefore should be allowed. Accordingly, the applicants respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Claims 4-9 have been objected to under Rule 75. This issue need not be addressed at the present time in view of the deletion of claims 4-9.

Claims 1-20 have been rejected under the first paragraph of Section 112 as lacking enablement with respect to the breadth of such claims. This rejection is respectfully traversed.

The PTO agrees that applicants' specification enables administration of the compound GM-611 to improve defecation function and to accelerate defecation. Applicants' claims now so conform! On the other hand, the rejection alleges that applicants' specification "fails to provide support for the prevention of defecation dysfunction or the

treatment of any defecation dysfunction other than that subsequent to morphine administration."

Applicants strongly traverse this latter conclusion. The issue is not "support", but is enablement. Moreover, the above quoted statement from the rejection is clearly incorrect as applicants' specification absolutely provides "support" for broadly treating and/or preventing defecation dysfunction in a patient, such support being not only in the original claims, but also in the many broad statements of the invention which appear throughout applicants' specification, e.g. the first paragraph on page 1.

Insofar as enablement is concerned, the first paragraph of Section 112 permits routine experimentation by those skilled in the art based on an applicant's disclosure; and, even if it were true that applicants' specification only **proves** efficacy for the prevention or treatment of defecation dysfunction only subsequent to morphine administration (which is incorrect), it would not be beyond the skills of those having skill in the present art to use applicants' invention (based on applicants' disclosure) for the more general prevention or treatment of defecation dysfunctions with little or no (and certainly no more than "routine") experimentation.

But actually the applicants have gone further. Thus, the present specification discloses specific

experimental results indicating the effects of GM-611 not only for relieving constipation caused by the administration of morphine (Example 2), but also for accelerating defecation in normal subjects (Examples 1, 3 and 4). In particular, taking into consideration the effect for accelerating defecation in a normal subject, the results indicate that GM-611 has pharmaceutical effect for treating constipation in general by accelerating defecation, and that such effect is not limited to treating morphine-induced constipation.

As regards the active agent, claim 10 has been amended to specify compound GM-611 by reciting that R_1 is isopropyl and R_2 is methyl.

There should be no question as to enablement, and the rejection should be withdrawn. Such is respectfully requested.

Claims 1-20 have been rejected under Section 102 as anticipated by the abstract of the Peeters article, Citation V, hereinafter simply "Peeters". Attached please find a full text copy of Peeters. The rejection is respectfully traversed.

The rejection states that Peeters discloses the use of GM-611 to treat gastric motility disorders, and that the drug promotes peristalsis in the gastrointestinal tract. From

this, the PTO concludes that applicants' claims are anticipated, i.e. lack novelty.

According to the Peeters' abstract, GM-611 is being developed as a potential treatment for gastric motility disorder, a well as reflux esophagitis, non-ulcer dyspepdia and diabetic gastroparesis. On the other hand, this abstract does not include any reference to the effect of GM-611 for treating constipation. Further, applicants also note that Peeters states that "GM-611 acts by a novel mechanism whereby it stimulates and promotes peristalsis in the stomach and other segments of the gastrointestinal tract". However, the abstract does not include any reference as to whether the effect of GM-611 over peristalsis in the gastrointestinal tract relates to treatment of constipation.

The full text of Peeters article also does not disclose any use of GM-611 for the treatment of constipation. There is no anticipation, and applicants' define novel subject matter over Peeters.

Accordingly, the rejection should be withdrawn, and such is respectfully requested.

No rejection under Section 103 has been imposed on the basis of Peeters, and applicants agree that the claimed invention would not have been obvious from Peeters. The present application discloses the effect of DM-611 for

treating constipation in mammals, particularly humans. Further, according to the experimental result of Example 1, GM-611 surprisingly accelerates normal defecation without increasing water content of stool. Thus, Fig. 2 of the application indicates that water content of stool does not depend on the dose of GM-611, while Fig. 4 indicate significant increase of water content of stool after administration of sennoside at a dose of 48 mg/kg and clear dose response in the water content 4-8h after administration of sennoside. As referred to on page 4, line 27 to page 5, line 24 in the present specification, the effect for accelerating normal defecation is significantly beneficial for reducing discomfort and for improving GOL of patients.

It can therefore be accurately said that it is clear that Peeters not only does **not** anticipate the claimed subject matter, but also does not make the claimed subject matter obvious.

A review of applicants' file has revealed that an IDS has not been submitted with respect to the publications mentioned in applicants' specification. Accordingly, such an IDS will be filed within the next several days.

The prior art documents made of record and not relied upon by the PTO have been noted, along with the

implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicants' claims.

Applicant believes that all issues raised in the Official Action have been addressed above in a manner that should lead to patentability of the present application. Favorable consideration and early formal allowance are respectfully requested.

Respectfully submitted,

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